

5092746

510(k) SUMMARY

NanoPass's MicronJet 600

FEB - 3 2010

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

NanoPass Technologies Ltd.
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Date Prepared: September 8, 2009

Name of Device and Name/Address of Sponsor

MicronJet 600

NanoPass Technologies Ltd.
3 Golda Meir St. Nes Ziona, Israel

Common or Usual Name

Microneedles Device

Classification Name

Hypodermic Single Lumen Needle, Product Code FMI, 21 C.F.R. § 880.5570

Piston Syringe, Product Code FMF, 21 C.F.R. § 880.5860

Device Trade Name:

MicronJet 600 Needle

Predicate Devices

1. Terumo Medical Corporation – Terumo Allergy Syringe (K980796)
2. BD Medical Surgical – BD PrecisionGlide™ (K021475)
3. Becton Dickinson SafetyGlide™ Syringe (K992734)

Intended Use / Indications for Use

The MicronJet 600 is intended to be used for injecting fluids into parts of the body below the surface of the skin. The MicronJet 600 is indicated for use in intradermal injections of any substance or drug approved for intradermal delivery.

Technological Characteristics

The MicronJet 600 Needle is a small plastic adapter (female luer) equipped with a chip having three microneedles designed to mate with any standard syringe (Luer Slip or Luer Lock). The MicronJet 600 is a sterile, single use device.

Performance Testing

Bench, animal and clinical testing was performed to assess the safety and effectiveness of the device for the stated indications for use. Performance testing demonstrated that the MicronJet 600 is as safe and effective as the predicate devices.

Substantial Equivalence

The MicronJet 600 is substantially equivalent to its predicate devices (Terumo Allergy Syringe (K980796), BD PrecisionGlide™ hypodermic needle (K021475), and SafetyGlide™ Syringe (K992734)). The MicronJet 600 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the MicronJet 600 and its predicate devices raise no new issues of safety or effectiveness. Performance data generated by the Company and detailed further in this notification, demonstrate that the MicronJet 600 is as safe and effective as its predicates for the stated indication. Thus, the MicronJet 600 is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Nanopass Technologies, Limited
C/O Mr. Jonathan Kahan
Regulatory Counsel
Hogan & Hartson LLP
555 13th Street NW
Washington, District of Columbia 20004

FEB - 3 2010

Re: K092746
Trade/Device Name: MicronJet 600
Regulation Number: 21CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 8, 2009
Received: September 8, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Anthony D. Watson
Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 092746

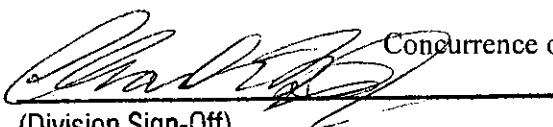
Device Name: MicronJet 600

Indications for Use:

The MicronJet 600 is intended to be used for injecting fluids into parts of the body below the surface of the skin. The MicronJet 600 is indicated for intradermal injections of any substance or drug approved for this delivery route.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 092746